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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,869	07/18/2003	Suresh K. Tikoo	293102003600	2929

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	04/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,869	TIKOO, SURESH K.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 22, 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Notice regarding the examination of patent applications containing nucleotide sequences, published March 27, 2007 in the Official Gazette of the USPTO, Vol. 1316, No. 4.

DETAILED ACTION

1. Applicant's preliminary amendment filed June 22, 2006 is acknowledged and entered. Claims 1-64 remain pending. In the PTO-90C mailed May 15, 2006, mailed prior to a response to the restriction requirement, the Office indicated that the restriction requirement mailed January 26, 2006 was vacated. This application was then found to be non-compliant with the sequence rules regarding the nucleotide sequences disclosed in the specification and/or claims, which Applicant has now complied with.

The restriction requirement is set forth below. Applicant is pointed to the Notice regarding the examination of patent applications containing nucleotide sequences, published March 27, 2007 in the Office Gazette of the USPTO, Vol. 1316, No. 4. A copy of the Notice is attached to this restriction requirement.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 4-6, 8, 9, 11-15, 17-39, 56, 57, 59, 60, 62 and 63, drawn to a motif comprising **AAATT**, classified in class 536, subclass 23.1. In claims 2, 6, 9 and 15, Applicant is required to elect one species construct selected from SEQ ID NO: 1, 2, 91, 103-139. (For example, Applicant may elect SEQ ID NO: 1, cggaaattcccgcaca. If, after search and examination, the claims reciting SEQ ID NO: 1 are deemed allowable, the Office will then search SEQ ID NO: 2, and so on.)

II. Claims 1, 2, 4-6, 8, 9, 11-15, 17-39, 56, 57, 59, 60, 62 and 63, drawn to a motif comprising **ATTT**, classified in class 536, subclass 23.1. In claims 2, 6, 9 and 15, Applicant is required to elect one species construct selected from SEQ ID NO: 3, 4, 95, 140-181.

III. Claims 1, 2, 4-6, 8, 9, 11-15, 17-39, 56, 57, 59, 60, 62 and 63, drawn to a motif comprising **TATT**, classified in class 536, subclass 23.1. In claims 2, 6, 9 and 15, Applicant is required to elect one species construct selected from SEQ ID NO: 5, 6, 97, 182-223.

IV. Claims 1, 2, 4-6, 8, 9, 11-15, 17-39, 56, 57, 59, 60, 62 and 63, drawn to a motif comprising **TATTTTTT**, classified in class 536, subclass 23.1. In claims 2, 6, 9 and 15, Applicant is required to elect one species construct selected from SEQ ID NO: 7, 8, 100, 224-255.

V. Claims 1, 2, 4-6, 8, 9, 11-15, 17-39, 56, 57, 59, 60, 62 and 63, drawn to a motif comprising **TATATA**, classified in class 536, subclass 23.1. In claims 2, 6, 9 and 15, Applicant is required to elect one species construct selected from SEQ ID NO: 9, 10, 101, 256-292.

VI. Claims 1, 2, 4-6, 8, 9, 11-15, 17-39, 56, 57, 59, 60, 62 and 63, drawn to a motif comprising **TTTT**, classified in class 536, subclass 23.1. In claims 2, 6, 9 and 15, Applicant is required to elect one species construct selected from SEQ ID NO: 11, 12, 99, 102, 293-333.

VII. Claims 1, 3-5, 7, 8, 10-14, 16-39, 56, 57, 59, 60, 62 and 63, drawn to a motif comprising **TATTTT**, classified in class 536, subclass 23.1. In claims 3, 7, 10

and 16, Applicant is required to elect one species construct selected from SEQ ID NO: 13, 334-348.

VIII. Claims 1, 3-5, 7, 8, 10-14, 16-39, 56, 57, 59, 60, 62 and 63, drawn to a motif comprising **ATATT**, classified in class 536, subclass 23.1. In claims 3, 7, 10 and 16, Applicant is required to elect one species construct selected from SEQ ID NO: 14, 349-353.

IX. Claims 1, 3-5, 7, 8, 10-14, 16-39, 56, 57, 59, 60, 62 and 63, drawn to a motif comprising **TTTA**, classified in 536, subclass 23.1. In claims 3, 7, 10 and 16, Applicant is required to elect one species construct selected from SEQ ID NO: 15, 354-364.

X. Claims 1, 3-5, 7, 8, 10-14, 16-39, 56, 57, 59, 60, 62 and 63, drawn to a motif comprising **AAATTTTA**, classified in class 536, subclass 23.1. In claims 3, 7, 10 and 16, Applicant is required to elect one species construct selected from SEQ ID NO: 16, 365-375.

XI. Claims 1, 3-5, 7, 8, 10-14, 16-39, 56, 57, 59, 60, 62 and 63, drawn to a motif comprising **ATTTTT**, classified in class 536, subclass 23.1. In claims 3, 7, 10 and 16, Applicant is required to elect one species construct selected from SEQ ID NO: 17, 376-394.

XII. Claims 1, 3-5, 7, 8, 10-14, 16-39, 56, 57, 59, 60, 62 and 63, drawn to a motif comprising **TATTTATT**, classified in class 536, subclass 23.1. In claims 3, 7, 10 and 16, Applicant is required to elect one species construct selected from SEQ ID NO: 18, 20, 395-413.

XIII. Claims 40-41, drawn to a method of eliciting an immune response, classified in class 435, subclass 5. Applicant is required to elect a vector construct having a single motif from claim 11. (Should Applicant amend the claims of this invention to recite species of the elected motif, a species election of one nucleotide sequence will be required.)

XIV. Claims 42-54, 58, 61 and 64, drawn to a recombinant porcine adenovirus vector comprising a deletion and/or addition of part or all of one or more E1 transcriptional control region, classified in class 435, subclass 320.1.

XV. Claims 55, drawn to a method of eliciting an immune response using a recombinant porcine adenovirus vector comprising a deletion and/or addition of part or all of one or more E1 transcriptional control region, classified in class 435, subclass 5.

3. The inventions are distinct, each from the other because of the following reasons:

a) Groups I-XII are all drawn to distinct nucleotide sequences having different motifs. Applicant is required to elect of one motif. **This is not a species election**. However, the election of a SEQ ID NO: within the motif is a species election. Each SEQ ID NO: is a patentably distinct species because each sequence has different nucleic acid content, thus presenting a serious search burden on the Office resources (see OG Notice attached).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
The resources of the Patent Office are not equipped to search multiple sequences for any given application. A search for all of the possible sequences instantly claimed would be a serious burden.

b) Groups (I-XII) and XIII are related as product and process of use. Groups XIV and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleotide sequences of Groups (I-XII) and the vectors of Group IX can be used in a materially different method of use, such as probes, or in the case of the adenovirus containing the nucleotide sequence, a detection assay.

c) Groups (I-XII) and XIV are unrelated inventions. The deletion in the viruses of Group XIV does not correspond to the deletions referred to in Groups I-XII. A search for both sets of

viruses would be a serious burden because literature pertinent to one Group will not necessarily reveal the other Group.

d) Groups (I-XII) and XV are unrelated inventions, as are Groups XIII and XIV. The viruses of Groups I-XII are not required to practice the method of Group XV. Likewise, the viruses of Group XIV are not required to practice the method of Group XIII.

Because these inventions are distinct for the reasons given above and the literature and sequence search required for one Group is not co-extensive for any other Group, and therefore a serious burden, restriction for examination purposes as indicated is proper. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet

all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

5. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 4/19/07
STACY B. CHEN
PRIMARY EXAMINER

Notice – Official Gazette of the USPTO Vol. 1316 No. 4 3/27/07

Examination of Patent Applications Containing Nucleotide Sequences

I. Summary

The United States Patent and Trademark Office (Office) published an Official Gazette notice in November of 1996 providing a partial waiver of the requirements for restriction pursuant to 37 CFR 1.141 et seq. and for unity of invention determinations pursuant to 37 CFR 1.475 et seq. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 Off. Gaz. Pat. Office 68 (Nov. 19, 1996) (1996 Notice). The 1996 Notice permitted examination of a reasonable number, normally up to ten, independent and distinct molecules described by their nucleotide sequence in a single patent application. The Office has reconsidered the policy set forth in the 1996 Notice in view of changes in the complexity of applications filed, the types of inventions claimed and the state of the prior art in this technology since that time. Because of these changes, the search and examination of up to ten molecules described by their nucleotide sequence often consumes a disproportionate amount of Office resources over that expended in 1996. Consequently, with this Notice the Office rescinds the partial waiver of 37 CFR 1.141 et seq. for restriction practice in national applications filed under 35 U.S.C. 111(a), and 37 CFR 1.475 et seq. for unity of invention determinations in both PCT international applications and the resulting national stage applications under 35 U.S.C. 371. This Notice is effective immediately and is applicable to all pending applications. Note, however, that supplemental restriction requirements will not be advanced in applications that have already received an action on their merits in the absence of extenuating circumstances.

II. Background

In 1996, the Office held public hearings to address concerns relating to patent protection of nucleic acids described by their nucleotide sequences. The ease of using automated techniques for sequencing large numbers of nucleotides resulted in the filing of a growing number of patent applications, many of which recited thousands of individual nucleotide sequences. After the public hearings, the Office modified its restriction and unity of invention practice for the examination of patent applications that claim large numbers of polynucleotide molecules described by their nucleotide sequences in an effort to encourage and promote growth in this technology while taking into account the unprecedented search and examination challenges that such applications pose.

In the 1996 Notice, the Office partially waived the requirements of 37 CFR 1.141(a) and permitted applicant to claim and have examined in a single application a reasonable number, normally up to ten, independent and distinct inventions described by their nucleotide sequences. At that time, the Office determined that such a practice would not create an undue burden on the Office and would promote efficient, cost effective examination of these types of applications. The Office made a similar revision to practice for search and examination of applications filed under the PCT. Pursuant to the partial waiver of 37 CFR 1.475 et seq., up to ten nucleotide sequences would be searched

and/or examined in international applications or national stage applications filed under 35 U.S.C. 371; where applicants paid a fee for search and/or examination of at least one additional group (see 37 CFR 1.476(b)), up to four additional sequences would be searched and/or examined per group.

Patent applications that prompted the public hearings and the 1996 Notice often disclosed multiple partially characterized complementary DNA (cDNA) molecules, discovered by expressed sequence tag (EST) techniques, that were claimed and described by simple reference to a nucleotide sequence. At that time, and in many of those applications, little information was provided relating to function of the nucleic acid, nor was there significant description of the function or the information content (e.g., protein coding capacity) of the nucleic acid claimed. Consequently such claims were, in many instances, simple in format and narrow in scope. Often, the examination of narrowly drawn claims to EST-type nucleic acid molecules required little more than automated database searches. Further, the review and analysis of sequence search results could be accomplished within examination time constraints.

Since 1996, the technology has evolved and the types of nucleic acid sequence-based claims have become more diverse and complex. In 1996, polynucleotide molecules were often claimed by simple reference to a nucleotide sequence. Polynucleotide molecules are now often claimed in a single application in a variety of complex formats, some of which may embrace multiple inventions, such as by reference to: the amino acid sequence of the protein encoded; the ATCC number of a deposited plasmid containing the polynucleotide molecule; arbitrary laboratory designations; function of the nucleic acid alone or in combination with a partial linear nucleotide sequence; a genus described in terms of homology, percent identity, or hybridization; a genus (or subgenus) described by nucleic acid sequence with variable positions specified within the sequence listing; single nucleotide polymorphisms (SNPs); antisense; or interfering RNA. .

Advances over the past ten years in automated sequencing and polynucleotide characterization techniques have made such activities routine. The entire genome of several organisms, including humans, has been determined and deposited into nucleotide sequence databases. Consequently, patent applications claiming large numbers of lengthy polynucleotides, such as full-length open reading frames and entire genomes, have become more the norm rather than the exception. The advances in nucleic acid sequencing techniques have also lead to the exponential growth in the size of nucleic acid sequence databases and an increase in the number and complexity of such databases.

The GenBank® database in 1996 contained 651,972,984 nucleotides in 1,021,211 sequences. In 2000 the database contained 11,101,066,288 nucleotides in 10,106,023 sequences, about a seventeen-fold increase in the number of nucleotides and about a ten-fold increase in the number of sequences. In February 2006, the GenBank database contained 59,750,386,305 bases in 54,584,635 sequence records or about a ninty-one-fold increase in the number of nucleotides and about a fifty-four-fold increase in the number of sequences.

These factors are responsible for exacerbating the search and examination burden faced by the Office with respect to polynucleotide inventions claimed and described in currently filed applications. It now requires significantly more computational time to run individual nucleotide sequence searches for examination purposes than in 1996, and there is significantly more pertinent prior art to consider. In addition, it currently takes more Office resources to correlate the claimed polynucleotide with the polynucleotide as defined in the prior art because it is increasingly common for both patent applicants and prior art references to describe a polynucleotide molecule in different ways.

The foregoing illustrate that the evolution of the technology and current claim drafting practices are placing an ever-growing resource burden on the Office to search and examine patent applications disclosing and claiming nucleotide sequences. Rescission of the1996 Notice is intended to enhance the Office's ability to provide a focused, thorough and quality examination of polynucleotide inventions, and to lead to consistency in the examination of polynucleotide molecules, regardless of the manner in which they are claimed, and equitable use of Office computational and examination resources. .

III. Examination Guidelines

For National applications filed under 35 U.S.C. 111(a), polynucleotide inventions will be considered for restriction, rejoinder and examination practice in accordance with the standards set forth in MPEP Chapter 800 (except for MPEP 803.04 which is superceded by this Notice). Claims to polynucleotide molecules will be considered for independence, relatedness, distinction and burden as for claims to any other type of molecule.

For International applications and national stage filings of international applications under 35 U.S.C. 371, unity of invention determination will be made in view of PCT Rule 13.2, 37 CFR 1.475 and Chapter 10 of the ISPE Guidelines. Unity of invention will exist when the polynucleotide molecules, as claimed, share a general inventive concept, i.e., share a technical feature which makes a contribution over the prior art.

Date: 02/22/07

/S/
John Doll
Commissioner for Patents